

The President's Emergency Plan For AIDS Relief (PEPFAR) Scientific Advisory Board Summary of Meeting

October 7 and 8, 2020

The President's Emergency Plan For AIDS Relief (PEPFAR) Scientific Advisory Board (SAB) was convened on October 7 and October 8, 2020, virtually, using Cisco WebEx.

The SAB serves the U.S. Global AIDS Coordinator in a solely advisory capacity concerning scientific, implementation, and policy issues related to the global response to HIV/AIDS. In accordance with the provisions of Public Law 92-463, the meeting was open to the public at all times, both days.

Board members participation:

Auerbach, Judith	Maxwell, Celia
Abdool Karim, Quarraisha	Milan, Jesse
Berman, Peter – not present 10/8	Mushavi, Angela
Celum, Connie	Nabiryo, Christine
Currier, Judith	Njoroge, Nyambura
Del Rio, Carlos	Pape, Jean
Emini, Emilio	Peters, David
Gruskin, Sofia – not present 10/8	Sanders, Edwin – not present
Harrington, Mark	Sawe, Fredrick
Kanyoro, Musimbi	Schmid, Carl – not present 10/7
Karita, Etienne	Siemens, Albert
Kates, Jennifer	Treston, Carole
Lockett, Lejeune	Warren, Mitchell
Macklin, Ruth - not present 10/8	Wiesman, John – not present
Mayer, Kenneth	

The State Department's Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC) staffing the meeting:

Sara Klucking, Designated Federal Officer
Crystal Solomon, Events Coordinator
Emily Coard, Technical Staff
Carolina Rodriguez Colon, Technical Staff

Presenters and Principals from S/GAC:

Deborah Birx, U.S. Global AIDS Coordinator
Angeli Achrekar, Principal Deputy Coordinator
Katy Godfrey, Senior Adviser
Rachel Golin, Senior Adviser (Acting)

DAY ONE: October 7, 2020

The SAB agenda on October 7 was focused on PEPFAR implementation during 2020 and the delivery of HIV services in the context of COVID-19. Dr. Klucking opened the meeting by taking roll call and handed off to the Chair, Dr. Carlos del Rio. Dr. del Rio welcomed the Board members and the viewing audience and invited Ambassador Deborah Birx to make her presentation.

Ambassador Birx welcomed and thanked the Board members for their service and their commitment to global health. She then moved into her presentation entitled “State of the PEPFAR Program and Priorities”.

PEPFAR Program Overview Presentation Points:

The Ambassador’s presentation included updates on PEPFAR programs, progress toward epidemic control, and PEPFAR’s operations and program impact from and response to the global COVID-19 pandemic.

- PEPFAR’s data-driven approach, focus on core policies essential to support clients, and focus on supporting indigenous local partners, put PEPFAR countries in a better position to sustain our collective gains through this very difficult time
- PEPFAR used both quantitative and qualitative data to react swiftly
- Three key goals for 2020 (pre COVID-19)
 - **Sustain the gains** in countries that have achieved HIV epidemic control (greater than 90/90/90) and **ensure treatment continuity**
 - **Accelerate control** in the handful of countries that are not on the brink of control
 - **Address the rising new infections** or slow progress of new infections in **key population epidemics** around the globe
- Priorities such as viral load coverage, retention (treatment continuity), community led monitoring, TB Tx and TPT, pediatrics, DREAMS, PrEP, Cervical Cancer screening, VMMC, Key Populations, and local partner transitions were discussed and COVID-19 impacts were highlighted throughout the data presentation slide section.
- The three key 2020 goals were made more challenging by COVID-19. PEPFAR is focused on these goals, maintaining and supporting progress and:
 - Ensuring ongoing deep coordination with the Global Fund and community
 - Leveraging PEPFAR-supported health systems and infrastructure to support partner countries with their COVID-19 response while maintaining HIV services
 - Adapting differentiated service delivery to protect clients and health systems
 - Emphasizing convenient, client-centered care (MMD, virtual platforms, decentralized drug delivery, empower communities)
- A PEPFAR Short Term Task Team (ST3), comprised of senior agency thought leaders was stood up in early March to provide adaptive guidance to PEPFAR teams on a weekly basis from early March to present. Guidance is publicly posted first twice weekly and now weekly to support the teams (<https://www.state.gov/pepfar/coronavirus/>).

Q&A with Board members followed the Ambassador’s presentation.

PEPFAR Program Overview Q&A Points:

- There is concern that KP populations and other vulnerable populations are at increased risk.
- There is concern that prevention services gets short shrift to treatment including VMMC, DREAMS, PMTCT (viral load access and coverage, pregnant and breastfeeding women).

The Ambassador departed the meeting at 10:30 am. Board members next discussed HIV Treatment and Prevention Service Delivery in the Context of COVID-19, moderated by the Chair. During the discussion the Board focused on the following Actions:

PEPFAR Program Overview SAB Actions:

- **Produce a document that summarizes best practices and lessons learned on continuing quality care for PLHIV during COVID-19**
- **Issue a Statement on the integral role of international collaboration** recommending continued and close relationships with entities such as Global Fund and the World Health Organization (WHO). There is a need to understand any limitations to a public statement. Ideally, final recommendations will go to PACHA as well as the Ambassador and State Department leadership.

Other considerations raised by the Board:

- Would S/GAC assemble data on the impact of lockdown on TB outcomes, TB preventive therapy, etc.? This would provide more nuances in our thinking about integrated HIV/TB treatment
- Would S/GAC articulate and discuss what we might expect to see in 2021 (increasing numbers of PLHIV, etc.) given the challenges in achieving PEPFAR targets due to COVID-19 lockdowns?
- COVID-19 is escalating stigma and discrimination in some regards (ex: travel to clinic during shutdown alerts others to HIV status). S/GAC should look at implications of escalating stigma for PEPFAR programming
- Is there data that could yield insight into intersecting impacts of multiple epidemics: epi, programmatic data, case studies on countries and locations that have successfully handled COVID-19, HIV, &/or TB despite challenges?
- Would S/GAC provide additional analyses on the challenge of VL & pregnant women? (Provided October 8, 2020)
- Does PEPFAR have data on the economic impact of COVID-19 that could impact HIV-related indicators?
- S/GAC should catalog the positive policies emerging and/or being accelerated due to COVID-19
- S/GAC should be on guard for provider and health worker burnout, ability to handle further challenges due to COVID-19

Dr. Klucking adjourned day one of the meeting, October 7, at 1 pm EDT.

DAY TWO: October 8, 2020

The SAB agenda on October 8 was focused on five key technical areas: New Biomedical Preventions, Children and Adolescents LHIV, HIV Treatment Considerations, New HIV Treatments, and Summary Comments & Closing. Dr. Klucking opened the meeting by taking roll call and handed off to the Chair, Dr. Carlos del Rio. Dr. del Rio welcomed the Board members and the viewing audience and invited Principal Deputy Coordinator Angeli Achrekar to provide a welcome. Dr. Achrekar brought Ambassador Bix's

greetings and welcomed and thanked the Board members for their service and for their contributions. She then handed back to Dr. del Rio who invited Mitchell Warren, SAB Board member and Executive Director of the AIDS Vaccine Advocacy Coalition (AVAC) to make his presentation entitled “The Next-Generation of Biomedical Prevention: Now What?”

New Biomedical Preventions Presentation Points:

Dr. Warren presented an update on the biomedical prevention product pipeline and proposed recommendations for S/GAC. He described the importance of options and choice and a balanced prevention portfolio. He detailed the product pipeline, key product considerations, key people considerations, and the distinctions between the three. Looking at the timelines and products he then focused on two products currently moving quickly through the regulatory approvals process, getting closer to the marketplace: the Dapivirine Vaginal Ring (DVR, “the Ring”) and injectable long-acting Cabotegravir (CAB-LA).

Lastly, Dr. Warren identified the implications/considerations for PEPFAR:

- No one option will be THE choice for all people, all the time – or for one person, all the time
- Biomedical product use & coverage need not be perfect to have impact
- It is time for PEPFAR to integrate DVR in prevention (Px) programming, other products as trials proceed
- Fill the product introduction gaps:
 - Accelerate time from regulatory approval to intro to impact
 - Demand-creation for prevention generally
 - Differentiated (and integrated) service delivery for Px
- Fill the product development gaps:
 - Longer-acting & event-driven
 - User-friendly & developed WITH users
 - Dual-purpose & multi-purpose methods
- Build Px platforms with oral TDF/FTC programs that can integrate DVR – while assessing specific service delivery needs that might be needed for an injectable.

New Biomedical Preventions Q&A Points:

- Need to collect and analyze PEPFAR experience/data to understand options for roll out of new biomedical options. The SAB can help OGAC develop clear guidance
 - Separate qualitative research from the clinical trial(s) would inform guidance.
 - As PEPFAR thinks about future targets, a coverage target might not be appropriate for this in early days. Better indicator: x amount of countries with trained providers and options.
 - Need for demand marketing and behavior change communication so people know about these options. PEPFAR could really help guide and drive this change.
- Programmatic delivery costs are still unclear. PEPFAR can assist in understanding how costs could be shared and fully inform MOHs before decisions are made.
- Is there an implementation research agenda at PEPFAR? Can SAB make recommendations around future pipeline (especially dual/multi-purpose methods)? Ex: non-hormonal contraceptive ring with ARVs

- PEPFAR should develop an implementation research agenda around novel biomedical prevention strategies to understand the policy environment, system needs, provider needs, and user preferences
- Strategy should be to implement new prevention options in the context of existing, robust health systems and interventions already working for PEPFAR
- Is there opportunity to partner with NIH for implementation research? Need landscape analyses and to understand cultural environment.

New Biomedical Preventions SAB Actions:

- **Recommend: S/GAC should move forward with implementing new biomedical prevention options.**
 - S/GAC should develop clear guidance
 - Work with Governments and MOHs on policy, costs and benefits to support product additions and adoption.
- **Recommend: S/GAC should develop an implementation research agenda around novel biomedical prevention strategies**
 - Research agenda should look at system needs, provider needs, and user preferences.
 - Leverage existing PEPFAR platforms such as DREAMS, Key Population programs, Family Planning, etc.
 - Agenda should build upon the existing PEPFAR systems and interventions.

Next, Dr. del Rio invited Dr. Rachel Golin, S/GAC Senior Adviser for Pediatric Care and Treatment (acting) to make her presentation entitled “Focusing on Children and Adolescents Living with HIV”.

Children and Adolescents LHIV Presentation Points:

Dr. Golin provided an overview of PEPFAR’s pediatric and adolescent HIV program focusing on both programmatic achievements and gaps.

- Treatment coverage among children and adolescents living with HIV (C/ALHIV) lags behind adult treatment coverage in most of the sub-Saharan African countries with large HIV epidemics
- There are persistent challenges in meeting testing, linkage to treatment, and treatment continuation/suppression targets
- Index testing, early infant diagnosis (EID), multi month dispensing, and improved ART regimens are showing promise in addressing challenges
- PEPFAR is moving forward on these interventions:
 - Index testing -- facilitate appropriate HIV testing for all biological children of adult ART clients.
 - Implement ART optimization (DTG 50 mg, TLD for adolescents) and transition to pediatric dolutegravir 10 mg dispersible tablets in 2021.
 - Focus on client centered differentiated service deliver to mitigate treatment interruption through a mix of preventive and responsive interventions
 - Ensure OVC addresses C/ALHIV and their families.

Children and Adolescents LHIV Q&A Points:

- We must interface with education players/entities to optimize care.

- Differentiated service delivery for adolescents: Are there unique experiences where this is being handled in a non-clinical setting (more youth friendly environment)?
 - A non-clinical setting would allow for provision of other psychosocial support
- Experiences of successful DSD models that are peer led for adolescents living with HIV: recommend scaling up. Peers living with HIV supporting other adolescents living with HIV.

Children and Adolescents LHIV SAB Actions:

- **Recommend: S/GAC should move forward on the effort to close gaps in pediatric and adolescent treatment of HIV**

Next, Dr. del Rio, invited Dr. Catherine (Katy) Godfrey, S/GAC Senior Adviser for Adult Care and Treatment to make her presentation entitled “Adult Treatment Updates”.

HIV Treatment Presentation Points:

Dr. Godfrey provided an overview of PEPFAR’s adult HIV treatment program focusing first on a few language updates, then approach to advanced disease, newer ART agents, and mortality.

Language is moving to be inclusive, non-judgmental emphasizing the “therapeutic alliance”. This moves from adherence and retention language to stress the continuity of and continuum of care including describing “lost to follow-up” as treatment interruption.

Advanced disease considerations focused mainly on the use of CD4 testing. Use of CD4 testing by PEPFAR in the age of “Test and Treat” has been limited. However, substantial PLHIV present with advanced disease and recognizing advanced disease for treatment can improve mortality. Individuals with advanced disease include both new ART clients but also those returning to care. Proposal: PEPFAR should expand CD4 testing to individuals returning to care after 1 year in adults and adolescents using Visitec tests, a rapid and more affordable </> 200 CD4 test.

The newer agents discussion focused on the pharmacological profile of TAF/FTC vs. ABC/3TC. Proposal: PEPFAR should use TAF as an alternative to ABC in adults and adolescents who cannot take TDF. However, TAF is not recommended as first line therapy for all because of the issues with rifampicin and pregnancy.

Lastly, Dr. Godfrey discussed the “fourth 90” referring to healthy living with HIV and focusing on understanding mortality. As countries reach epidemic control, PEPFAR is looking more closely at mortality including issues of continuity of care, TB Tx and TPT, and cervical cancer screening. PEPFAR is collecting and evaluating more data under the TX_ML indicator and is capturing qualitative information under cause of death.

HIV Treatment Q&A Points:

- PEPFAR should look to partner with other organizations to address comorbidity issues
- CD4 testing- focus should be on what’s best for the patient. Goal should be: to get to a point where we can offer CD4 testing at the time of diagnosis to provide best care
- PEPFAR should note that different areas will have a different composition of advanced disease
- PEPFAR might consider operational research to generate data on prevalence of NCDs in aging PLHIV on ART. Countries are now structuring support groups for the older PLHIV in care

HIV Treatment SAB Actions:

- **Recommend: S/GAC should move forward with implementing an expansion of CD4 testing**
- **Recommend: S/GAC should move forward with using TAF as an alternative to ABC**

Next, Dr. del Rio moved into his presentation entitled “Long-acting antiretrovirals for HIV Treatment”.

New HIV Treatments Presentation Points:

Daily oral ART has had a substantial impact on treatment and prevention of HIV however adherence remains a major obstacle. Long-acting or extended-release nanoprecipitates of antiretroviral therapies given on a monthly or less frequent basis have the potential to play a key part in HIV treatment and prevention, particularly in populations where poor adherence hinders successful treatment. Formulations of cabotegravir and rilpivirine are advancing through clinical trials. Dr. del Rio proceeded to review the science on CAB-LA and RPV-LA including the ATLAS study and the FLAIR study status updates.

New HIV Treatments Q&A Points:

- Can we learn from implementation in Canada (where long acting injectable have been approved)?

New HIV Treatments SAB Actions:

- **Recommend: S/GAC should track the progress of new long acting treatments and associated implementation considerations**

Next, Dr. del Rio invited public comment. Dr. Benny Kottiri, USAID, was the sole public commenter. He followed up on the biomedical prevention discussion to request that the SAB come up with more specific, focused recommendations related to the implementation science research agenda. By when can PEPFAR expect to have additional technical guidance from the SAB?

Dr. del Rio then summarized action items and identified other business priorities of the SAB for review and discussion.

SAB ACTIONS SUMMARY:

- **SAB should produce a document that summarizes best practices and lessons learned on continuing quality care for PLHIV during COVID-19**
- **SAB should issue a statement on the integral role of international collaboration**
- **Recommend: S/GAC should move forward with implementing new biomedical prevention options.**
- **Recommend: S/GAC should develop an implementation research agenda around novel biomedical prevention strategies**
- **Recommend: S/GAC should move forward on the effort to close gaps in pediatric and adolescent treatment of HIV**
- **Recommend: S/GAC should move forward with implementing an expansion of CD4 testing**
- **Recommend: S/GAC should move forward with using TAF as an alternative to ABC**

- **Recommend: S/GAC should track the progress of new long acting treatments and associated implementation considerations**

SAB Additional Actions Discussion:

Any SAB public statement should:

- Reiterate how important PEPFAR is for HIV and for COVID (why PEPFAR has contributed so much). Provide kudos to S/GAC for work of HQ and field
- Emphasize science, emphasize international cooperation (GF, WHO etc.)
- Be widely disseminated to include PACHA, public, and other administration leadership.
- COVID considerations:
 - Leverage the trust that already exists in PEPFAR
 - Highlight opportunity to use PEPFAR for COVID vaccine delivery
 - Leverage investment in networks among stakeholders and have pipelines in place that could absorb COVID outreach
 - Look at the symbiotic relationship (COVID and HIV) and how they are interrelated

Closing Remarks:

Next, Dr. del Rio provided a few closing remarks, thanking the Board members and inviting Dr. Achrekar to provide brief closing remarks. Dr. Achrekar extended her appreciation to the board, and that of the Ambassador. The SAB is important to S/GAC to understand how we can improve program impact. Our program benefits greatly from the input from and close collaboration with the SAB, international partners and the community.

Dr. Klucking adjourned day two of the meeting, October 8, 2020 at approximately noon EDT.